

SIDE-TOP ELECTRODE

STATEMENT OF GOVERNMENT SUPPORT

5 The present invention was reduced to practice, in part, with government support under SBIR grant no. 2R44DC0461402A1 awarded by the Small Business Research Program of the Department of Health and Human Services. The United States Government has certain rights in the invention.

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RELATED APPLICATIONS

This application is a continuation-in-part of application serial no. 10/012,230 filed December 6, 2001.

15 BACKGROUND OF THE INVENTION

Today, there are many prospective applications for a high-density multi-electrode biocompatible implant. One of the most important is for a cochlear implant. The cochlea is a snail shaped organ of the inner ear that translates
20 sound waves into bioelectrical nerve impulses. A cochlear implant, by directly electrically stimulating the cochlea can effect hearing restoration in persons otherwise completely deaf and for whom other methods of hearing restoration would be ineffective. Compared to the cochlea,
25 however, which includes approximately 30,000 receptive nerve endings, currently available cochlear implants are crude devices, capable of stimulating the cochlea with a degree of selectivity far beneath what the cochlea is capable of accommodating. Accordingly, in order to effect
30 a more complete hearing restoration, cochlear implants having a higher density of precisely positioned electrode contact points are needed.

Because the cochlea has so many more sensing sites than an implant could possibly have electrode contact points, it is desirable to stimulate the cochlea at points between electrode contact points. This can be effected by
5 "field shaping," in which neighboring electrode contact points are separately controlled to form an electric field that has its maximum at a desired cochlear stimulation point. Unfortunately, in order to perform field shaping it is generally desirable to have electrode contact points
10 that are spaced apart by no more than a few hundred μm . Achieving this fine spacing of electrode contact points has proven a challenge to researchers.

The cochlea is not the only site within the body where a high-density implant could be of use, however. The
15 brain, the retina and the heart are just a few other sites within the body where such an implant could be used. Some implants may have to operate for many years without failure. Unfortunately, providing such an implant proves to be quite difficult in practice.

20 Among the challenges encountered in the construction of an implant having a large number (>30) of closely spaced ($< 200 \mu\text{m}$) and precisely positioned electrode contact points is the problem of decomposition in the body due to attack by the body's interstitial fluid (ISF). Any
25 seam in an implant will be attacked by ISF and may eventually come apart. Because of this, it is extremely important that biocompatible materials be used throughout an implant. Moreover, the more that an implant can take the form of a seamless, unitary whole the longer an
30 implant can be expected to last within the body. This requirement conflicts with the greater level of complexity desired of implants.

Researchers at the University of Michigan have designed one type of probe that is currently under test. This probe is made by micro-machining a silicon substrate using photolithographic techniques in order to achieve
5 accurate positioning of closely spaced electrode contact points. Unfortunately the materials used are stiff and brittle. Accordingly this probe is not well suited for an application that requires flexibility, such as a cochlear implant.

10 Additionally, multilayer printed circuit board (PCB) technology has advanced so that multilayer structures having traces on the order of microns thick are now available. There are a number of reasons, however, why this technology has, in general, not been applied to the
15 biomedical arena. First, many of the materials used in PCB manufacture are not biocompatible, or degrade after implantation. Second, even flex circuits made from polyimide, a flexible dielectric, typically do not have the degree of flexibility necessary to facilitate the
20 construction and placement of a cochlear implant.

Accordingly, there is a long-standing, unresolved need for a biocompatible, long-term implant that can precisely stimulate a sensory bodily organ, such as the cochlea.

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SUMMARY

In a first separate aspect, the present invention is a bio-implant having a length and a proximal and a distal end. The bio-implant includes at least two laminae of
30 dielectric material that are joined together, thereby defining a boundary and that also define a side surface that is intersected by the boundary. The laminae also

define a nominal top surface that meets the side surface. At least one set of conductors is interposed between the laminae and extends lengthwise from the proximal end toward the distal end, each one of the set of conductors
5 being terminated at the side surface to form a set of conductor terminations. Additionally, a set of electrode contacts is defined, each constructed on the side surface and extending over a portion of the nominal top surface, each of the electrode contacts contacting one of the
10 conductor terminations.

In a second separate aspect, the present invention is a method of constructing a bio-implant having a length and a proximal and a distal end. The method uses a first and second laminae of dielectric material, each laminae
15 defining a top surface, a laminae side surface and a bottom surface, a proximal end and a distal end. At least one set of conductors is created on the top surface of the first laminae. These conductors extend lengthwise from the proximal end toward the distal end, each one of the set of
20 conductors is terminated adjacent to the side surface to form a set of conductor terminations. The top surface of the second laminae is adhered to the bottom surface of the first laminae about the set of conductors, thereby forming a work piece and defining a boundary and also defining a
25 joined side surface that is intersected by the boundary, and a work piece top surface that is the top surface of the first laminae. Finally, a set of electrode contacts is constructed on the joined side surface and also on the work piece top surface, each the electrode contact point
30 contacting a one of the conductor terminations.

The foregoing and other objectives, features and advantages of the invention will be more readily

understood upon consideration of the following detailed description of the invention, taken in conjunction with the accompanying drawings.

5 BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view of a bio-implant according to the present invention.

FIG. 2 is a perspective view of the bio-implant of FIG. 1.

10 FIG. 3 is a perspective view of a workpiece used for the production of a helical bio-implant according to the present invention.

FIG. 4 is a perspective view of a helical bio-implant produced using the workpiece of FIG. 3.

15 FIG. 5 is a perspective view of a mold adapted to produce a helical bio-implant according to the present invention.

FIG. 6 is a perspective view of a helical bio-implant formed in the mold of FIG. 5.

20 FIG. 7 is a perspective view of an alternative preferred embodiment of a bio-implant.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

25 Referring to FIGS. 1-3 an electrode contact point bearing implant 10 having a proximal end 16 and a distal end 18 includes a set of first laminae 12 made of a dielectric material, for example, liquid crystal polymer (LCP). Conductive traces 14 that extend longitudinally
30 from proximal end 16 toward distal end 18 are constructed on each first laminae 12.

A set of second laminae 13 is interspersed with the set of first laminae 12, electrically isolating one set of traces 14 from another. Second laminae 13 are made of LCP having a lower melting point than the LCP of first laminae 12. As a result, the implant 10 can be heated after being assembled to melt second laminae 13, thereby causing the entire structure to fuse together without surrendering the structural stability provided by first laminae 12.

Each of the conductive traces 14, after it has extended its full longitudinal extent, turns toward an electrode contact point bearing side 20 of the implant 10 and extends to a position either proximal to or abutting side 20. An electrode contact point 22 in the form of a width-wise portion of a plated via is connected to each trace at side 20.

Skilled persons will readily perceive traces 14 could be routed so that the implant 10 could taper inwardly toward the electrode contact point bearing side 20 as it extends from its proximal end 16 to its distal end 18.

Alternatively the electrode contact point bearing side 20 could taper inwardly toward the distal end 18. In addition as not all laminae bear traces 14 all the way to the distal end 18, implant 10 could taper inwardly from top to bottom or from bottom to top as it extends distally.

Tapering embodiments are of particular importance with respect to cochlear implants, because the cochlea, the prospective location of such an implant, tapers inwardly as it curls towards its center.

In one preferred method of making implant 10, a further margin (not shown) is originally included in the workpiece from which implant 10 is made. Vias are drilled through this margin, so as to contact the termini of the

traces 18. The vias are plated with conductive material and then the margin is removed either by mechanical or other means, using for example, an ND:YAG laser. The plated vias are thus bisected to form electrode contact points 22. It should be noted that the vias that are drilled need not be round. If it was found that a square sided via or an elliptical via resulted in electrode contact points 22 having superior electromagnetic properties, these could be formed.

In another preferred method of making implant 10, side 18 is turned to face a laser, which machines a set of indents that are then plated with conductive material to form electrode contact points 22. Persons skilled in the art can recognize that the areas between electrode contact points can be masked during the plating operation, or can be plated and then stripped of plating, for example, by laser ablation or chemical etching. With this method, the electrode contact points could be formed to have differing depths over their top-to-bottom extent.

The electrode contact points may be created by any of a number of well known techniques including sputter deposition, electroless or electrolytic (electroplating) deposition. An inert base metalization can be applied by one of the above means, followed by deposition of a selective metal suitable for neural excitation, including iridium or iridium oxide. Iridium oxide can be deposited on the base metal for example by sputter deposition, by electroplating or by activation. Iridium may be built up through cyclic voltametry. Surfaces may be plasma etched prior to sputtering, to increase adhesion.

In a preferred embodiment, laminae 12 and 13 are 12 μm (0.5 mils) thick. In a preferred embodiment 8 first

laminae are included in implant 10. Conductive traces 14 are 125 μm (5 mils) wide and 5 μm (0.2 mils) thick. Eight traces 14 are accommodated per laminae 12, for a total of 64 traces and 64 electrode contact points. Electrode
5 contact points 22 are made by forming vias having a diameter of 30 μm (1.2 mils) thick, electroplating these vias and bisecting them using a laser. The electrode contact points are spaced 200 μm (8 mils) apart. In one preferred embodiment, implant 10 is sheathed at the top
10 and bottom with a separate dielectric layer such as LCP or silicone, that is 80 μm (3 mils) thick.

A typical, and challenging, application for an electrode bearing implant, such as implant 10, is as a cochlear implant. One of the great challenges of creating
15 a cochlear implant is creating a structure that is helical and may be straightened for purposes of insertion but will then resume its helical shape. A characteristic of laminaeted structures is that they tend to bend more easily along the plane that intersects the laminae, than
20 along the plane that is parallel with the laminae.

Referring to FIG. 3, one approach to creating a cochlear implant is to create a laminaeted structure 50 that extends far enough in two dimensions to accommodate a cochlear spiral shape 52. The structure 50 is built with
25 traces 14 in spiral shape within structure 50. Traces 14 terminate on the interior surface 56 of spiral shape 52, which is cut from structure 50, to form a helical implant 58. The electrode contact points 22 in this instance may be constructed on the side of and/or on top of helical
30 implant 58 to make as close as contact as possible with the receptive neurons or nerve cells, located along the upper and inner side of the scala media. The helical

implant 58 may then be heat formed, by placing it in a helical mold 60, either by itself or with a charge of silicone and or LCP. Helical mold 60 is made of a center conical part 62 and two halves 64 that meet about part 62.

5 In an alternative preferred embodiment implant 10 is originally made straight, as in FIG. 1, and then placed in the helical mold 60, curling in the plane that intersects the laminae. Mold 60 may be heated to form implant 10 into a spiral structure 66. This structure could then be
10 straightened for insertion, but would have shape memory to revert to a spiral or helical shape after insertion.

Referring to FIG. 7, in an alternative preferred embodiment of a bio-implant 110 (commonly referred to as "electrode" in the industry), electrode contacts 122 are
15 formed to extend along side 120 and onto nominal top surface 116. Because bio-implant 110 can be more easily curved in dimension transverse to the laminae planes, this permits the electrode contacts 122 to be positioned so that they optimally stimulate the nerve endings, after
20 curvature has been imparted to bio-implant 110 (if bio-implant 110 is more specifically a cochlear implant). The portions of electrode contacts 122 that adhere to side 120 provide a robust means of electrical conduction to the portions on nominal top surface 116 and also may stimulate
25 the auditory nerve endings themselves, as the auditory nerve endings are not entirely on either the inner side or the top of the scala media, but are, in part, located at the curvature between the side and the top. If desired, electrode contacts on side surface 120 can be covered by
30 dielectric material, such as silicone, in a molding process, leaving only electrode contacts on top surface 116 active.

The terms and expressions which have been employed in the foregoing specification are used as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of
5 excluding equivalents of the features shown and described or portions thereof, it being recognized that the scope of the invention is defined and limited only by the claims which follow.